

§ 870.4475 Surgical vessel dilator.

(a) *Identification.* A surgical vessel dilator is a device used to enlarge or calibrate a vessel.

(b) *Classification.* Class II (performance standards).

§ 870.4500 Cardiovascular surgical instruments.

(a) *Identification.* Cardiovascular surgical instruments are surgical instruments that have special features for use in cardiovascular surgery. These devices include, e.g., forceps, retractors, and scissors.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907, Feb. 5, 1980, as amended at 54 FR 25049, June 12, 1989; 66 FR 38797, July 25, 2001]

§ 870.4875 Intraluminal artery stripper.

(a) *Identification.* An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriosclerotic arteries.)

(b) *Classification.* Class II (performance standards).

§ 870.4885 External vein stripper.

(a) *Identification.* An external vein stripper is an extravascular device used to remove a section of a vein.

(b) *Classification.* Class II (performance standards).

Subpart F—Cardiovascular Therapeutic Devices

§ 870.5050 Patient care suction apparatus.

(a) *Identification.* A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.

(b) *Classification.* Class II (performance standards).

§ 870.5100 Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter.

(a) *Standard PTCA Catheter—(1) Identification.* A PTCA catheter is a device

that operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. A PTCA balloon catheter has a single or double lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use. A PTCA catheter is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

(2) *Classification.* Class II (special controls). The special control for this device is “Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters.” See § 870.1(e) for the availability of this guidance document.

(b) *Cutting/scoring PTCA Catheter—(1) Identification.* A cutting/scoring PTCA catheter is a balloon-tipped catheter with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis.

(2) *Classification.* Class III (premarket approval). As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 870.3.

[75 FR 54496, Sept. 8, 2010]